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PATENT APPLICATION
Docket No. 7678.350.2

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:		)
		)
	Steven D. Jensen et al.	)
		)
Serial No.:	09/710,181	) Art Unit
		) 1616
Filed:	November 10, 2000	)
		)
Confirmation No.:	4245	)
		)
For:	COMPOSITIONS AND METHODS FOR WHITENING AND DESENSITIZING TEETH	)
		)
Examiner:	Alton Nathaniel Pryor	)
		)
Customer No.:	022913	)

APPEAL BRIEF

MAIL STOP APPEAL BRIEF – PATENTS
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

This is an appeal to the Board of Patent Appeals and Interferences (the "Board") from the Final Office Action mailed July 18, 2011 (the "Final Action") in the above-identified patent application ("Subject Application"). A Notice of Appeal is being timely filed herewith.

I. REAL PARTY IN INTEREST

The real party in interest is Ultradent Products, Inc.

II. RELATED APPEALS, INTERFERENCES AND JUDICIAL PROCEEDINGS

Pending Appeal of U.S. Patent Application Serial No. 11/733,490

III. STATUS OF CLAIMS

Claims 1-40 are cancelled.

Claims 41, 42, 44-48, 50-54, 56-63, 65-68, 70-87, and 91-94 currently stand rejected.

Claims 41, 42, 44-48, 50-54, 56-63, 65-68, 70-87, and 91-94 are being appealed.

IV. STATUS OF AMENDMENTS

None filed after the Final Rejection.

V. SUMMARY OF CLAIMED SUBJECT MATTER

The appealed claims of the Subject Application are generally directed towards dental bleaching compositions and related methods for bleaching and desensitizing teeth. The independent claims on appeal are claims 41, 59, 65, 72, 77, 81 and 86.

Independent Claim 41 is directed to a dental bleaching composition that is substantially free of abrasives (Application, p. 5 ll. 20-24) for non-abrasively bleaching and desensitizing a person's teeth (*Id.* at p. 5, ll. 1-5). The composition comprises a dental bleaching agent in an amount in a range of 10% to about 30% by weight of the dental bleaching composition (*Id.* at p. 3 ll. 7, p. 25 ll. 23, p. 26 ll. 22, p. 27 ll. 21-23, p. 29 ll. 17-18, and p. 18 ll. 24 – p. 19 ll. 1) so as to have a tooth bleaching effect when contacted with a person's teeth, said dental bleaching agent comprising at least one peroxide (*Id.* at p. 10 ll. 4-6 and p. 18 ll. 19-21), potassium nitrate in a range of about 0.01% to less than 2% by weight of the dental bleaching composition (*Id.* at p. 8 ll. 18-19, p. 12 ll. 11, p. 13 ll. 8-9, p. 29 ll. 12-13) so as to result in reduced tooth sensitivity that may be caused by said dental bleaching agent in the absence of said potassium nitrate when the dental bleaching composition is contacted with a person's teeth for a time sufficient to bleach teeth (*Id.* at p. 5, ll. 2-5). The dental bleaching composition also includes a carrier into which the dental bleaching agent and the potassium nitrate are dispersed (*Id.* at p. 5 ll. 11-12). The carrier is free of an amount of an abrasive

that would externally abrade a tooth surface such that the dental bleaching composition does not externally abrade a tooth surface when applied thereto (*Id.* at p. 5 ll. 20 – p. 6 ll. 2 and p. 20 ll. 1-7). The carrier comprises a solvent and a tackifying agent (*Id.* at p. 6 ll. 14-19).

Independent Claim 59 is directed to a dental bleaching composition that is substantially free of abrasives (Application, p. 5 ll. 20-24) for non-abrasively bleaching and desensitizing a person's teeth (*Id.* at p. 5, ll. 1-5). The composition comprises a dental bleaching agent in an amount in a range of 10% to about 20% by weight of the dental bleaching composition (*Id.* at p. 3 ll. 7, p. 25 ll. 23, p. 26 ll. 22, p. 27 ll. 21-23, p. 29 ll. 17-18, and p. 18 ll. 24 – p. 19 ll. 2) so as to have a tooth bleaching effect when contacted with a person's teeth, said dental bleaching agent comprising at least one peroxide (*Id.* at p. 10 ll. 4-6 and p. 18 ll. 19-21), potassium nitrate in a range of about 0.05% to about 1% by weight of the dental bleaching composition (*Id.* at p. 8 ll. 20, p. 13 ll. 9-10, p. 29 ll. 12-13) so as to result in reduced tooth sensitivity that may be caused by said dental bleaching agent in the absence of said potassium nitrate when the dental bleaching composition is passively maintained in contact with a person's teeth for at least about 15 minutes without brushing or scrubbing (*Id.* at p. 5, ll. 2-5, p. 5 ll. 20 – p. 6 ll. 2, p. 10 ll. 7, and p. 36 ll. 8-11). The dental bleaching composition also includes a carrier into which the dental bleaching agent and the potassium nitrate are dispersed (*Id.* at p. 5 ll. 11-12). The carrier is free of an amount of an abrasive that would externally abrade a tooth surface such that the dental bleaching composition does not externally abrade a tooth surface when applied thereto (*Id.* at p. 5 ll. 20 – p. 6 ll. 2 and p. 20 ll. 1-7). The carrier comprises a solvent and a tackifying agent (*Id.* at p. 6 ll. 14-19).

Independent Claim 65 is directed to a dental bleaching composition that is substantially free of abrasives (Application, p. 5 ll. 20-24) for non-abrasively bleaching and desensitizing a person's teeth (*Id.* at p. 5, ll. 1-5). The composition comprises a dental bleaching agent in an amount in a range of 10% to about 30% by weight of the dental bleaching composition (*Id.* at p. 3 ll. 7, p. 25 ll. 23, p. 26 ll. 22, p. 27 ll. 21-23, p. 29 ll. 17-18, and p. 18 ll. 24 – p. 19 ll. 1) so as to have a tooth bleaching effect when contacted with a person's teeth, said dental bleaching agent comprising at least one peroxide (*Id.* at p. 10 ll. 4-6 and p. 18 ll. 19-21), potassium nitrate in an amount of about 0.5% by weight of the dental bleaching composition (*Id.* at p. 8 ll. 21, p. 10 ll. 13, p. 26 ll. 21, and p. 33 ll. 17) so as to result in reduced tooth sensitivity that may be caused by said dental bleaching agent in the absence of said potassium nitrate when the dental bleaching composition is contacted with a person's teeth for a time sufficient to bleach teeth (*Id.* at p. 5, ll. 2-5). The dental bleaching

composition also includes a carrier into which the dental bleaching agent and the potassium nitrate are dispersed (*Id.* at p. 5 ll. 11-12). The carrier is free of an amount of an abrasive that would externally abrade a tooth surface such that the dental bleaching composition does not externally abrade a tooth surface when applied thereto (*Id.* at p. 5 ll. 20 – p. 6 ll. 2 and p. 20 ll. 1-7). The carrier comprises a solvent and a tackifying agent (*Id.* at p. 6 ll. 14-19).

Independent Claim 72 is directed to a method for non-abrasively bleaching and desensitizing a person's teeth (*Id.* at p. 5, ll. 1-5). The method comprises providing a non-abrasive dental bleaching composition that comprises a dental bleaching agent in an amount in a range of 10% to about 30% by weight of the dental bleaching composition (*Id.* at p. 3 ll. 7, p. 25 ll. 23, p. 26 ll. 22, p. 27 ll. 21-23, p. 29 ll. 17-18, p. 18 ll. 24 – p. 19 ll. 1, and p. 37 ll. 1-4) so as to have a tooth bleaching effect when contacted with a person's teeth, said dental bleaching agent comprising at least one peroxide (*Id.* at p. 10 ll. 4-6 and p. 18 ll. 19-21), potassium nitrate in a range of about 0.01% to less than 2% by weight of the dental bleaching composition (*Id.* at p. 8 ll. 18-19, p. 12 ll. 11, p. 13 ll. 8-9, p. 29 ll. 12-13) so as to result in reduced tooth sensitivity that may be caused by said dental bleaching agent in the absence of said potassium nitrate when the dental bleaching composition is contacted with a person's teeth for a time sufficient to bleach teeth (*Id.* at p. 5, ll. 2-5). The dental bleaching composition also includes a carrier into which the dental bleaching agent and the potassium nitrate are dispersed (*Id.* at p. 5 ll. 11-12). The carrier is free of an amount of an abrasive that would externally abrade a tooth surface such that the dental bleaching composition does not externally abrade a tooth surface when applied thereto (*Id.* at p. 5 ll. 20 – p. 6 ll. 2 and p. 20 ll. 1-7). The carrier comprises a solvent and a tackifying agent (*Id.* at p. 6 ll. 14-19). The method further comprises contacting the person's teeth with said non-abrasive dental bleaching composition without scrubbing or brushing for a time sufficient to bleach teeth and in a manner so as to not abrade the person's teeth, said potassium nitrate reducing tooth sensitivity that may be caused by said dental bleaching agent in the absence of said potassium nitrate (*Id.* at p. 37 ll. 11-15).

Independent Claim 77 is directed to a method for non-abrasively bleaching and desensitizing a person's teeth (*Id.* at p. 5, ll. 1-5). The method comprises providing a non-abrasive dental bleaching composition that comprises a dental bleaching agent in an amount in a range of 10% to about 20% by weight of the dental bleaching composition (*Id.* at p. 3 ll. 7, p. 25 ll. 23, p. 26 ll. 22, p. 27 ll. 21-23, p. 29 ll. 17-18, and p. 18 ll. 24 – p. 19 ll. 2) so as to have a tooth bleaching effect when contacted with a person's teeth, said dental bleaching agent comprising at least one peroxide (*Id.* at

p. 10 ll. 4-6 and p. 18 ll. 19-21), potassium nitrate in a range of about 0.05% to about 1% by weight of the dental bleaching composition (*Id.* at p. 8 ll. 20, p. 13 ll. 9-10, p. 29 ll. 12-13) so as to result in reduced tooth sensitivity that may be caused by said dental bleaching agent in the absence of said potassium nitrate when the dental bleaching composition is contacted with a person's teeth for a time sufficient to bleach teeth (*Id.* at p. 5, ll. 2-5). The dental bleaching composition also includes a carrier into which the dental bleaching agent and the potassium nitrate are dispersed (*Id.* at p. 5 ll. 11-12). The carrier is free of an amount of an abrasive that would externally abrade a tooth surface such that the dental bleaching composition does not externally abrade a tooth surface when applied thereto (*Id.* at p. 5 ll. 20 – p. 6 ll. 2 and p. 20 ll. 1-7). The carrier comprises a solvent and a tackifying agent (*Id.* at p. 6 ll. 14-19). The method further comprises contacting the person's teeth with said non-abrasive dental bleaching composition for at least about 15 minutes without scrubbing or brushing and in a manner so as to not abrade the person's teeth, said potassium nitrate reducing tooth sensitivity that may be caused by said dental bleaching agent in the absence of said potassium nitrate (*Id.* at p. 10 ll. 7 and p. 37 ll. 11-19).

Independent Claim 81 is directed to a method for non-abrasively bleaching and desensitizing a person's teeth (*Id.* at p. 5, ll. 1-5). The method comprises providing a non-abrasive dental bleaching composition that comprises a dental bleaching agent in an amount in a range of 10% to about 30% by weight of the dental bleaching composition (*Id.* at p. 3 ll. 7, p. 25 ll. 23, p. 26 ll. 22, p. 27 ll. 21-23, p. 29 ll. 17-18, p. 18 ll. 24 – p. 19 ll. 1, and p. 37 ll. 1-4) so as to have a tooth bleaching effect when contacted with a person's teeth, said dental bleaching agent comprising at least one peroxide (*Id.* at p. 10 ll. 4-6 and p. 18 ll. 19-21), potassium nitrate in a range of about 0.5% by weight of the dental bleaching composition (*Id.* at p. 8 ll. 21, p. 10 ll. 13, p. 26 ll. 21, and p. 33 ll. 17) so as to result in reduced tooth sensitivity that may be caused by said dental bleaching agent in the absence of said potassium nitrate when the dental bleaching composition is contacted with a person's teeth for a time sufficient to bleach teeth (*Id.* at p. 5, ll. 2-5). The dental bleaching composition also includes a carrier into which the dental bleaching agent and the potassium nitrate are dispersed (*Id.* at p. 5 ll. 11-12). The carrier is free of an amount of an abrasive that would externally abrade a tooth surface such that the dental bleaching composition does not externally abrade a tooth surface when applied thereto (*Id.* at p. 5 ll. 20 – p. 6 ll. 2 and p. 20 ll. 1-7). The carrier comprises a solvent and a tackifying agent (*Id.* at p. 6 ll. 14-19). The method further comprises contacting the person's teeth with said non-abrasive dental bleaching composition without scrubbing or brushing for a desired

time period and in a manner so as to not abrade the person's teeth, said potassium nitrate reducing tooth sensitivity that may be caused by said dental bleaching agent in the absence of said potassium nitrate (*Id.* at p. 37 ll. 11-15).

Independent Claim 86 is directed to a sticky and viscous dental bleaching composition that is substantially free of abrasives (Application, p. 5 ll. 20-24 and p. 6 ll. 15) for non-abrasively bleaching and desensitizing a person's teeth. (*Id.* at p. 5, ll. 1-5). The composition comprises a dental bleaching agent in an amount in a range of 10% to about 20% by weight of the dental bleaching composition (*Id.* at p. 3 ll. 7, p. 25 ll. 23, p. 26 ll. 22, p. 27 ll. 21-23, p. 29 ll. 17-18, and p. 18 ll. 24 – p. 19 ll. 2) so as to have a tooth bleaching effect when contacted with a person's teeth, said dental bleaching agent comprising at least one peroxide (*Id.* at p. 10 ll. 4-6 and p. 18 ll. 19-21), potassium nitrate in a range of about 0.01% to less than 2% by weight of the dental bleaching composition (*Id.* at p. 8 ll. 18-19, p. 12 ll. 11, p. 13 ll. 8-9, p. 29 ll. 12-13) so as to result in reduced tooth sensitivity that may be caused by said dental bleaching agent in the absence of said potassium nitrate when the dental bleaching composition is contacted with a person's teeth for a time sufficient to bleach teeth (*Id.* at p. 5, ll. 2-5). The dental bleaching composition also includes a carrier into which the dental bleaching agent and the potassium nitrate are dispersed (*Id.* at p. 5 ll. 11-12). The carrier is free of an amount of an abrasive that would externally abrade a tooth surface such that the dental bleaching composition does not externally abrade a tooth surface when applied thereto (*Id.* at p. 5 ll. 20 – p. 6 ll. 2 and p. 20 ll. 1-7). The carrier comprises a solvent and a tackifying agent (*Id.* at p. 6 ll. 14-19).

Dependent claim 61 recites the same limitations as recited in independent claim 59, and further recites that the potassium nitrate has a concentration of about 0.5% by weight of the dental composition (*Id.* at p. 8 ll. 21, p. 10 ll. 13, p. 26 ll. 21, and p. 33 ll. 17).

Dependent claim 92 recites the same limitations as recited in independent claim 65, and further recites that the dental bleaching agent is included in a range of 10% to about 20% by weight of the dental bleaching composition (*Id.* at p. 3 ll. 7, p. 25 ll. 23, p. 26 ll. 22, p. 27 ll. 21-23, p. 29 ll. 17-18, and p. 18 ll. 24 – p. 19 ll. 2).

Dependent claim 91 recites the same limitations as recited in independent claim 59, and further recites that the dental bleaching agent is included in a range of 10% to about 15% by weight of the dental bleaching composition (*Id.* at p. 3 ll. 7, p. 25 ll. 23, p. 26 ll. 22, p. 27 ll. 21-24, p. 29 ll. 17-18, and, p. 30 ll. 21).

Dependent claim 94 recites the same limitations as recited in independent claim 41, and further recites that the potassium nitrate has a concentration of about 0.5% by weight of the dental composition (*Id.* at p. 8 ll. 21, p. 10 ll. 13, p. 26 ll. 21, and p. 33 ll. 17), and that the dental bleaching agent is included in a range of 10% to about 15% by weight of the dental bleaching composition (*Id.* at p. 3 ll. 7, p. 25 ll. 23, p. 26 ll. 22, p. 27 ll. 21-24, p. 29 ll. 17-18, and, p. 30 ll. 21).

Peroxides used to bleach teeth are known to cause irritation and tooth sensitivity for some people. *Id.* at p. 8, ll. 11-12. Including potassium nitrate in an amount within a narrowly tailored range on either side of 0.5% (e.g., 0.01% to less than 2%) has been shown, by comparative testing, to unexpectedly provide superior desensitization than bleaching compositions that include a greater amount of potassium nitrate. *Id.* at p. 8, ll. 12-13, 18-22; p. 9, ll. 7-13; p. 27, l. 11 – p. 29, l. 8; Fischer Declaration (Evidence Appendix), ¶¶ 11-17. The fact that including less potassium nitrate, a desensitizing agent, in a dental bleaching composition that also includes a peroxide tooth bleaching agent has been found to provide superior desensitization than including more potassium nitrate is counterintuitive, surprising and unexpected. *See* Application, p. 8, ll. 20-22; p. 10, ll. 10-13; p. 12, ll. 7-11.

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Issue 1: Whether claims 41, 42, 47, 48, 50-54, 56-58, 72-76 are unpatentable under 35 U.S.C. § 103(a) over Fischer et al. (US 5,851,512).

Issue 2: Whether claims 59-60, 62-63, and 77-80 are unpatentable under 35 U.S.C. § 103(a) over Fischer et al. (US 5,851,512).

Issue 3: Whether claims 46, 65-68, 70-71, 81-85 are unpatentable under 35 U.S.C. § 103(a) over Fischer et al. (US 5,851,512).

Issue 4: Whether claims 86-87 and 44 are unpatentable under 35 U.S.C. § 103(a) over Fischer et al. (US 5,851,512).

Issue 5: Whether claims 45 and 93 are unpatentable under 35 U.S.C. § 103(a) over Fischer et al. (US 5,851,512).

Issue 6: Whether claims 61 and 92 are unpatentable under 35 U.S.C. § 103(a) over Fischer et al. (US 5,851,512).

Issue 7: Whether claim 91 is unpatentable under 35 U.S.C. § 103(a) over Fischer et al. (US 5,851,512).

Issue 8: Whether claim 94 is unpatentable under 35 U.S.C. § 103(a) over Fischer et al. (US 5,851,512).

Issue 9: Whether claims 41, 42, 44-48, 50-54, 56-63, 65-68, 70-87 and 91-94 are unpatentable under obviousness type double patenting over the claims of U.S. Patent Nos. 5,851,512, 6,368,576, 6,039,625, and 6,306,370.

VII. ARGUMENT

A. Issue 1: Whether Claims 41, 42, 47, 48, 50-54, 56-58 and 72-76 Are Unpatentable Under 35 U.S.C. § 103(a) Over Fischer et al.

1. Comparative Testing Demonstrates That the Narrowly Defined Range of Potassium Nitrate Recited in Claims 41, 42, 47, 48, 50-54, 56-58 and 72-76 Unexpectedly And Unpredictably Provides Better Desensitization Than the Broad Ranges And Values Disclosed by Fischer et al.

U.S. Patent No. 5,851,512 to Fischer et al. is generally directed to dental compositions for treating sensitive teeth. The compositions typically include potassium nitrate dispersed into a sticky matrix carrier material (see Abstract of Fischer et al.). Generally, these compositions are used for treating teeth that already exhibit sensitivity or pain as a result of sickness, poor dental hygiene, or the use of peroxide bleaching agents (*Id.* at col. 1 ll. 34-37). Fischer et al. teaches broad ranges of potassium nitrate of from about 0.1% to about 10%, and more preferably 1% to about 7% by weight (*Id.* at col. 8 ll. 57-60). These compositions are not manufactured to include a peroxide, as Fischer et al. specifically teaches that "peroxides such as hydrogen peroxide and carbamide peroxide have been found to be unstable in the presence of potassium nitrate", but that "it may be possible to add peroxide to the dental compositions of the present invention shortly before treatment in order to combine the bleaching and/or antiseptic action of the peroxide with the desensitization action of the potassium nitrate" (see col. 9 ll. 35-41).

Example 8 of Fischer et al. discloses a desensitizing composition with 2% potassium nitrate, but which includes no peroxide bleaching agent, as this would be unstable. At col. 15 lines 8-11, Fischer et al. states that the Example 8 composition may be combined with urea peroxide (10 wt%) just prior to treatment to yield a dental composition having bleaching activity as well as desensitizing activity. As a first point, because Fischer et al. teaches that peroxides are unstable in the presence of potassium nitrate, it teaches away from providing a composition that includes both potassium nitrate and peroxide packaged together as a single part composition. Fischer et al. is actually a prior invention of Appellants. It has since been discovered that both potassium nitrate and peroxide may

stably be packaged together, and that the results noted in U.S. Patent No. 5,851,512 were likely the result of contamination.

Secondly, each of claims 41, 42, 47, 48, 50-54, 56-58, and 72-76 recites an amount of potassium nitrate in a range of about 0.01% to less than 2% by weight of the dental bleaching composition, and an amount of peroxide dental bleaching agent between 10% and about 30% by weight of the composition, which amounts are narrowly tailored around evidence of surprising and unexpected results associated with concentrations within these ranges.

As described in the present application, Appellants performed a comparative study and found that bleaching compositions that included 0.5% potassium nitrate and 10.5% bleaching agent unexpectedly resulted in substantially lower oral sensitivity compared to compositions that included 3% potassium nitrate and either 10.5% or 15% bleaching agent. The comparative study is explained on pages 26-29 of the Application and was the subject of a 37 C.F.R. § 131 declaration by Dan E. Fischer filed June 25, 2001 (*see* Evidence Apendix). Indeed, the Examiner is in agreement that the comparative study shows surprising and unexpected results (see Final Action p. 3-4) but has argued that the claims are not commensurate in scope with the comparative study because the claims recite ranges of 10% to about 30% bleaching agent and about 0.01% to less than 2% potassium nitrate.

Potassium nitrate is a well-known tooth desensitizing agent that is effective in relieving pain associated with sensitive teeth (Fischer Declaration, ¶ 7). Potassium nitrate has been used within desensitizing gels and dentrifices (*i.e.*, toothpaste) to relieve pain associated with sensitive teeth (*Id.* at ¶ 8; Application, p. 10, ll. 14-18). The standard concentration of potassium nitrate within desensitizing compositions is about 3-5% by weight (Fischer Declaration, ¶ 9). Desensitizing toothpaste compositions can include up to 10% by weight potassium nitrate (Application, p. 10, ll. 15-17). Since conventional dental desensitizing compositions typically include at least 3% potassium nitrate, there is no reason to doubt that such concentrations are effective in relieving pain associated with sensitive teeth. Indeed, when used alone, in the absence of a peroxide dental bleaching agent, 3% or more potassium nitrate is known to be effective in treating tooth sensitivity (*Id.* at p. 10, ll. 14-22; Fischer Declaration, ¶¶ 7-9, 11).

Because potassium nitrate is known to desensitize teeth, it stands to reason that including more potassium nitrate should provide greater relief to those who suffer from sensitive teeth, while

including less should provide a lesser amount of such relief.[1] Moreover, because potassium nitrate is known to be effective in treating sensitize teeth at concentrations of 3% and above, one of skill in the art would not expect potassium nitrate, when included in a standard amount of 3% to cause greater tooth and oral sensitivity than not including *any*, or even a lesser quantity of, potassium nitrate. Yet that is exactly what was surprisingly and unexpectedly found when using potassium nitrate in combination with a peroxide dental bleaching agent (Fischer Declaration, ¶¶ 14-17). In the case of dental bleaching compositions that contain a peroxide tooth bleaching agent and potassium nitrate as a tooth desensitizing agent, comparative testing has shown that the optimal quantity of potassium nitrate is only about 0.5% by weight of the composition (Application, p. 26, l. 12 – p. 29, l. 8; Fischer Declaration, ¶¶ 11-17). Dental bleaching compositions that include 0.5% potassium nitrate have been shown by comparative testing to provide superior tooth desensitization than bleaching compositions that include 3% potassium nitrate (Fischer Declaration, ¶ 17).

This is entirely counterintuitive in view of the known fact that potassium nitrate is known to be an effective tooth desensitizing agent when included in amounts of 3% or greater in compositions that do not include a peroxide bleaching agent (*Id.* at ¶¶ 16-17). Because potassium nitrate is a known desensitizing agent, one of skill in the art would have expected 3% potassium nitrate to be *more* effective in treating tooth sensitivity than only 0.5%, an amount that is only 1/6 as much as 3%. The fact that including *less* potassium nitrate was found to be *more* effective in treating tooth sensitivity than including more potassium nitrate is a surprising and unexpected result.

Even more unexpected and surprising was the finding in the comparative study that including 3% potassium nitrate within a dental bleaching composition was, in some cases, worse than including no potassium nitrate at all. Including 3% potassium nitrate within a dental bleaching composition containing a peroxide bleaching agent actually caused *increased* tooth sensitivity, on average, to hot or cold, as well as greater tongue sensitivity, compared to a bleaching composition containing *no* potassium nitrate (*Id.* ¶¶ 13-14). Thus, when included within a dental bleaching composition in an amount of 3% together with a dental bleaching agent, potassium nitrate ceases to act as a tooth desensitizing agent for at least some people suffering from tooth and other oral sensitivities caused by the peroxide dental bleaching agent (*Id.* at ¶ 15). That is also surprising, unexpected and entirely counterintuitive given the fact that potassium nitrate is known to be effective

[1] It is well-known, however, that many substances have diminishing returns. Therefore, one of skill in the art might assume there is an amount of potassium nitrate that provides maximum tooth desensitization and that including more potassium nitrate beyond that amount will not provide any significant increase in the desensitization effect.

in treating tooth sensitivity when included in amounts of 3% or greater in compositions that do not include a dental bleaching agent (*Id.* at ¶¶ 7-8, 16).

There is no rule or case law that requires Appellants to only claim the specific species used in the comparative study, and the Final Action cites to no rule or case law that would require this. To the contrary, MPEP § 716.02(d) states that "the nonobviousness of a broader claimed range can be supported by evidence based on unexpected results from testing a narrower range if one of ordinary skill in the art would be able to determine a trend in the exemplified data which would allow the artisan to reasonably extend the probative value thereof". In re Kollman, 595 F.2d 48, 56 201 USPQ 193 (CCPA 1979); In re Lindner, 457 F.2d 506, 509, 173 USPQ 356, 359 (CCPA 1972); In re Clemens, 622 F.2d 1029, 1036, 206 USPQ 289, 296 (CCPA 1980). The comparative testing described in the Application and Fischer Declaration provide such evidence, and the instant claims only claim narrowly tailored ranges that were extrapolated from the test data and are therefore commensurate in scope with the comparative test.

With respect to the narrowly tailored concentration range of peroxide bleaching agent, if using an amount of potassium nitrate (e.g., 0.5%) within the narrowly tailored concentration range of about 0.01% to less than 2% together with a commonly used amount of bleaching agent (e.g., about 10%) was more effective in mitigating oral sensitivity than would otherwise be caused by the dental bleaching agent than when a larger amount of potassium nitrate was used (i.e., 3%), it may reasonably be concluded that this trend would continue when larger (e.g., up to about 30%) or smaller amounts of the dental bleaching agent are used.

With respect to the narrowly tailored concentration ranges of potassium nitrate, because using 0.5% potassium nitrate unexpectedly resulted in reduced oral sensitivity compared to when either 3% or 0% is used, it is reasonable to conclude that an amount of potassium nitrate within a narrowly tailored range on either side of 0.5% would also provide greater desensitization compared to either 3% or 0% potassium nitrate.

In response to similar arguments presented to the Examiner in the immediately prior response, the Examiner states that "Applicants have not tested a range of potassium nitrate and bleaching agent, but rather tested only a single data point of 0.5% potassium nitrate and 10.5% carbamide peroxide." The Examiner further states that "the testing of a single data point is not enough data to deduce and make claim to a concentration trend for potassium nitrate and carbamide peroxide." (Final Action, p. 3-4).

Applicants have in fact tested more than simply a single data point of 0.5% potassium nitrate and 10.5% carbamide peroxide, as the comparative testing describes testing of the following four compositions:

(1) 0.5% potassium nitrate and 10.5% bleaching agent;

(2) 3% potassium nitrate 10% bleaching agent;

(3) 3% potassium nitrate and 15% bleaching agent;

(4) 0% potassium nitrate and 10% bleaching agent;

As described above, the range of tests performed shows that composition (1) (including 0.5% potassium nitrate and a typical bleaching agent concentration) provided better desensitization than each of the other compositions, and that compositions (2) and (3) (including 3% potassium nitrate and two different but typical bleaching agent concentrations) actually exhibited greater oral sensitivity than composition (4), which included no potassium nitrate at all.

Thus, based on the results, one can clearly deduce that some range of potassium nitrate with a lower end point greater than 0%, an upper endpoint less than 3%, and which includes 0.5% potassium nitrate, should also provide superior desensitization characteristics as compared to either 3% or 0% potassium nitrate. The recited range of 0.01% to less than 2% potassium nitrate is narrowly tailored based on these comparative testing results because 0.01% is significantly greater than 0% and <2% is less than 2/3 of 3% (<67%).

Appellant notes that claims 72-76 are similar to the composition claims grouped within Issue 1, but are method claims reciting a method by which the composition is provided and contacted with a person's teeth without scrubbing or brushing to reduce tooth sensitivity caused by the dental bleaching agent. These claims recite the same ranges of potassium nitrate and dental bleaching agent (i.e., about 0.01% to less than 2% potassium nitrate and 10% to about 30% peroxide dental bleaching agent) recited within the composition claims grouped in Issue 1.

B. Issue 2: Whether Claims 59-60, 62-63 And 77-80 Are Unpatentable Under 35 U.S.C. § 103(a) Over Fischer et al.

1. Comparative Testing Demonstrates That the Narrowly Defined Range of Potassium Nitrate Recited in Claims 59-60, 62-63, And 77-80 Unexpectedly And Unpredictably Provides Better Desensitization Than the Broad Range Disclosed by Fischer et al.

Appellant notes that claims 59-60 and 62-63 are similar to the claims discussed above in Issue 1, but recite even more restrictive ranges of both potassium nitrate and the peroxide dental

bleaching agent. Specifically, these claims recite a range of about 0.05% to about 1% potassium nitrate and 10% to about 20% peroxide dental bleaching agent. As described above relative to the group of claims discussed in Issue I, the comparative study provides evidence of surprising and unexpected results, and claims 59-60 and 62-63 are even more narrowly tailored around these results.

Appellant notes that method claims 77-80 recite similar composition limitations, and further recite method steps for providing and contacting the composition onto a person's teeth for at least about 15 minutes without scrubbing or brushing to reduce tooth sensitivity caused by the dental bleaching agent. These claims recite the same ranges of potassium nitrate and peroxide dental bleaching agent (i.e., about 0.05% to about 1% potassium nitrate and 10% to about 20% peroxide dental bleaching agent) recited within the composition claims grouped in Issue 2.

And, in any event, Fisher et al. does not teach or suggest the specific amounts of potassium nitrate and peroxide recited in the claims and is primarily only a potassium nitrate only technology, with peroxide bleach being an afterthought add on without regarding to what would be the optimum quantity of potassium nitrate when a peroxide bleaching agent is used. Fisher et al. certainly does nto teach or suggest using more potassium nitrate when used by itself and less potassium nitrate when peroxide is included. And to assert otherwise is to ignore the plain teachings of Fisher et al.

C. Issue 3: Whether Claims 46, 65-68, 70-71, 81-85 Are Unpatentable Under 35 U.S.C. § 103(a) Over Fischer et al.

1. Comparative Testing Demonstrates That the Narrowly Defined Range of Potassium Nitrate Recited in Claims 46 65-68, 70-71, And 81-85 Unexpectedly And Unpredictably Provides Better Desensitization Than the Broad Range Disclosed by Fischer et al.

Appellant notes that claims 46, 65-68, 70-71, and 81-85 are similar to the claims discussed above relative to Issue 1, but recite the most restrictive range of potassium nitrate (i.e., essentially the same as the tested amount of 0.5%). Specifically, these claims recite a value of *about* 0.5% potassium nitrate and 10% to about 30% peroxide dental bleaching agent. As described above relative to the group of claims discussed in Issue I, the comparative study provides evidence of surprising and unexpected results, and claims 46, 65-68, 70-71, and 81-85 recite the actual concentration of potassium nitrate shown to exhibit surprising and unexpected results coupled with a recited range of peroxide dental bleaching agent that is typically used within the art. As unexpected results have been shown for a combination of 0.5% potassium nitrate and 10.5% peroxide dental bleaching agent, one would expect similar beneficial results at higher peroxide bleaching agent concentrations (e.g., up to about 30%).

Appellant notes that claims 81-85 are similar to the composition claims grouped in Issue 3, but are method claims reciting a method by which the composition is provided and contacted with a person's teeth without scrubbing or brushing to reduce tooth sensitivity caused by the dental bleaching agent. These claims recite the same ranges of potassium nitrate and peroxide dental bleaching agent (i.e., about 0.5% potassium nitrate and 10% to about 30% peroxide dental bleaching agent) recited within the composition claims grouped in Issue 3.

D. Issue 4: Whether Claims 86-87 Are Unpatentable Under 35 U.S.C. § 103(a) Over Fischer et al.

1. Comparative Testing Demonstrates That the Narrowly Defined Range of Potassium Nitrate Recited in Claims 86-87 Unexpectedly And Unpredictably Provides Better Desensitization Than the Broad Range Disclosed by Fischer et al.

Appellant notes that claims 86-87 are similar to the claims discussed above relative to Issue 1, but recite a more restrictive range of peroxide dental bleaching agent. Specifically, these claims recite a range of 10% to about 20% peroxide dental bleaching agent. Appellant notes that compositions containing 10%, 10.5% and 15% peroxide were tested. As described above relative to the group of claims discussed in Issue I, the comparative study provides evidence of surprising and unexpected results, and claims 86-87 recite a range of peroxide dental bleaching agent that is even more narrowly tailored around this evidence.

E. Issue 5: Whether Claims 45 and 93 Are Unpatentable Under 35 U.S.C. § 103(a) Over Fischer et al.

1. Comparative Testing Demonstrates That the Narrowly Defined Range of Potassium Nitrate Recited in Claims 45 And 93 Unexpectedly And Unpredictably Provides Better Desensitization Than the Broad Range Disclosed by Fischer et al.

Appellant notes that claims 45 and 93 are similar to the claims discussed above relative to Issue 1, but recite a very restricted range of peroxide dental bleaching agent. Specifically, these claims recite a range of 10% to 15% peroxide dental bleaching agent. Again, Appellant tested composition having 10%, 10.5% and 15% peroxide. As described above relative to the group of claims discussed in Issue I, the comparative study provides evidence of surprising and unexpected results, and claims 45 and 93 recite a range of peroxide dental bleaching agent that is very narrowly tailored around this evidence.

F. **Issue 6: Whether Claims 61 And 92 Are Unpatentable Under 35 U.S.C. § 103(a) Over Fischer et al.**

1. ***Comparative Testing Demonstrates That the Narrowly Defined Range of Potassium Nitrate Recited in Claims 61 And 92 Unexpectedly And Unpredictably Provides Better Desensitization Than the Broad Range Disclosed by Fischer et al.***

Appellant notes that claims 61 and 92 are similar to the claims discussed above relative to Issue 2, but recite very restrictive ranges of both potassium nitrate. Specifically, these claims recite a value of about 0.5% potassium nitrate and 10% to about 20% peroxide dental bleaching agent. As described above relative to the group of claims discussed in Issue I, the comparative study provides evidence of surprising and unexpected results, and claims 61 and 92 recite the actual concentration of potassium nitrate shown to exhibit surprising and unexpected results coupled with a recited range of peroxide dental bleaching agent that is narrowly restricted relative to that concentration used in the comparative testing. As unexpected results have been shown for a combination of 0.5% potassium nitrate and 10.5% peroxide dental bleaching agent, one would expect similar beneficial results at somewhat higher peroxide bleaching agent concentrations (e.g., up to about 20%).

G. **Issue 7: Whether Claim 91 Is Unpatentable Under 35 U.S.C. § 103(a) Over Fischer et al.**

1. ***Comparative Testing Demonstrates That the Narrowly Defined Range of Potassium Nitrate Recited in Claim 91 Unexpectedly And Unpredictably Provides Better Desensitization Than the Broad Range Disclosed by Fischer et al.***

Appellant notes that claim 91 is similar to the claims discussed above relative to Issue 2, but recites restrictive ranges for both the peroxide dental bleaching agent and potassium nitrate. Specifically, this claim recites a range 0.05% to about 1% potassium nitrate and 10% to 15% peroxide dental bleaching agent. As described above relative to the group of claims discussed in Issue I, the comparative study provides evidence of surprising and unexpected results, and claim 91 is narrowly restricted relative to the concentration of potassium nitrate shown to have surprising and unexpected benefits while also being very narrowly restricted relative to the concentration of peroxide dental bleaching agent used in the comparative testing.

H. **Issue 8: Whether Claim 94 Is Unpatentable Under 35 U.S.C. § 103(a) Over Fischer et al.**

1. Comparative Testing Demonstrates That the Narrowly Defined Range of Potassium Nitrate Recited in Claim 94 Unexpectedly And Unpredictably Provides Better Desensitization Than the Broad Range Disclosed by Fischer et al.

Appellant notes that claim 94 is similar to the claims discussed above relative to Issue 1, but recites the most restricted ranges for potassium nitrate and peroxide dental bleaching agent. Specifically, this claim recites about 0.5% potassium nitrate and 10% to 15% peroxide dental bleaching agent. All recited range endpoints were tested as part of the comparative study. As described above relative to the group of claims discussed in Issue I, the comparative study provides evidence of surprising and unexpected results at 0.5% potassium nitrate and 10.5% peroxide dental bleaching agent, and claim 94 recites the actual concentration of potassium nitrate shown to exhibit unexpected results, and a range of peroxide dental bleaching agent that is very narrowly restricted relative to the concentration of peroxide dental bleaching agent used in the comparative testing.

I. **Issue 9: Whether claims 41, 42, 44-48, 50-54, 56-63, 65-68, 70-87 and 91-94 are unpatentable under obviousness type double patenting over the claims of U.S. Patent Nos. 5,851,512, 6,368,576, 6,039,625, and 6,306,370.**

1. None of Claims 1-12, 15, and 16 of U.S. Patent No. 5,851,512 recite a peroxide dental bleaching agent, as required by each of claims 41, 42, 44-48, 50-54, 56-63, 65-68, 70-87 and 91-94.

Claims 41, 42, 44-48, 50-54, 56-63, 65-68, 70-87, and 91-94 also stand rejected based on obviousness type double patenting over claims 1-12, 15, and 16 of U.S. Patent No. 5,851,512.

None of claims 1-12, 15, or 16 of the '512 patent recites a peroxide dental bleaching agent, which is required by every one of claims 41, 42, 44-48, 50-54, 56-63, 65-68, 70-87, and 91-94, but only potassium nitrate by itself. As such, the Examiner has failed to make a *prima facie* obviousness rejection of claims 41, 42, 44-48, 50-54, 56-63, 65-68, 70-87 and 91-94 based on claims 1-12, 15, and 16 of U.S. Patent No. 5,851,512.

2. ***Comparative Testing Demonstrates That the Narrowly Defined Ranges of Potassium Nitrate Recited in Claims 41, 42, 44-48, 50-54, 56-63, 65-68, 70-87 and 91-94 Unexpectedly And Unpredictably Provides Better Desensitization Than the Broad Ranges Within the Claims of Any of U.S. Patent Nos. 6,368,576, 6,039,625, and 6,306,370.***

Claims 41, 42, 44-48, 50-54, 56-63, 65-68, 70-87, and 91-94 also stand rejected based on obviousness type double patenting over various claims of U.S. Patent No. 5,368,576; U.S. Patent No. 6,309,625; and U.S. Patent No. 6,306,370.

None of the claims of any of these patents claim the specific recited ranges of 0.01% to less than 2% potassium nitrate, about 0.05% to about 1%, and particularly the 0.5% concentration for which the comparative testing showed surprising and unexpected results. For example, the *claims* of these various patents recite:

U.S. Patent No. 6,368,576 "up to about 10%" (claim 10)

U.S. Patent No. 6,309,625 "about 0.1 to about 50%" (claim 2)

U.S. Patent No. 6,306,370 "at least about 0.1%" (claim 1)

U.S. Patent No. 6,306,370 "about 1 to about 7%" (claim 2)

U.S. Patent No. 6,306,370 "about 0.1 to about 10%" (claims 14 & 16)

Appellants acknowledge that the broad ranges for potassium nitrate recited in the claims of the '576, '625, and '370 patents may have some overlap with the narrow ranges recited in the claims on appeal. That has never been disputed. It is for that reason that Appellants presented comparative test data showing that including a relatively small amount of potassium nitrate in combination with a dental bleaching agent used to bleach teeth surprisingly and unexpectedly resulted in a superior desensitization effect compared to using a greater amount of potassium nitrate within the ranges recited in the claims of the '576, '625, and '370 patents. The broad concentration ranges for potassium nitrate recited in the claims of the '576, '625, and '370 patents do not teach or suggest to one of skill in the art the desirability of including a relatively small quantity of potassium nitrate within the narrowly tailored ranges recited in the claims on appeal. The comparative study, because it demonstrates surprising and unexpected results for the narrow claimed ranges, is sufficient to rebut the allegation that the claims are *prima facie* obvious over the claims of the '576, '625, and '370 patents.

The disclosure of such claims is generally no better for supporting an obviousness-type double patenting rejection in light of the demonstrated surprising and unexpected results than the disclosure (i.e., 0.1% to about 10% and about 1% to about 7% potassium nitrate) within the

specification of U.S. Patent No. 5,851,512 described above relative to the 35 U.S.C. § 103(a) obviousness rejection over U.S. Patent No. 5,851,512.

In short, the claimed range of about 0.01 to less than 2% potassium nitrate is narrowly tailored around the comparative testing data showing unexpected results somewhere in a range of greater than 0% potassium nitrate and less than 3% potassium nitrate, and including 0.5% potassium nitrate. The claimed range of about 0.05% to about 1% potassium nitrate is even more narrowly tailored about this data, and the claimed range of about 0.5% potassium nitrate actually corresponds to the actual amount of potassium nitrate shown in the comparative testing to exhibit unexpected and surprising results.

One of skill in the art would reasonably expect such unexpected results to be associated with compositions including somewhat greater amounts of peroxide dental bleaching agent than the tested 10.5%, as well as the tested 10% and 15% values. Based on these results, one would reasonably expect a composition including 10% to about 30% peroxide dental bleaching agent and any of the restricted ranges of potassium nitrate to also exhibit improved desensitizing ability. More convincingly, based on the comparative testing results, one would reasonably expect a composition including 10% to about 20% peroxide dental bleaching agent and any of the restricted ranges of potassium nitrate to also exhibit improved desensitizing ability. Even more convincingly, based on the comparative testing results, one would reasonably expect a composition including 10% to about 15% peroxide dental bleaching agent and any of the restricted ranges of potassium nitrate to also exhibit improved desensitizing ability.

3. Comparative Testing Demonstrates That the Narrowly Defined Ranges of Potassium Nitrate Recited in Claims 61, Unexpectedly And Unpredictably Provides Better Desensitization Than the Broad Ranges Within the Claims of Any of U.S. Patent Nos. 6,368,576, 6,039,625, and 6,306,370.

Surely claim 61, which recites very restricted ranges of both potassium nitrate (e.g., about 0.5%) and a very restricted range of peroxide dental bleaching agent (10% to about 20%) is sufficiently narrowly tailored to be commensurate in scope with the evidence of surprising and unexpected results.

4. Comparative Testing Demonstrates That the Narrowly Defined Ranges of Potassium Nitrate Recited in Claims 94, Unexpectedly And Unpredictably Provides Better Desensitization Than the Broad Ranges Within the Claims of Any of U.S. Patent Nos. 6,368,576, 6,039,625, and 6,306,370.

Surely claim 94, which recites the most restrictive ranges for both potassium nitrate (e.g., about 0.5% in claim 94) and a very restricted ranges of peroxide dental bleaching agent (10% to

about 15% in claim 94) is sufficiently narrowly tailored to be commensurate in scope with the evidence of surprising and unexpected results.

CONCLUSION

Appellant notes that while not every contention, allegation and characterization of the Examiner set forth in the Final Action, or raised at any other time during the prosecution of this case, was specifically addressed herein, the lack of remarks concerning any particular contention, allegation or characterization advanced by the Examiner is not intended, and should not be construed, to constitute an admission or concession by Appellant.

For at least the reasons discussed herein, Appellant respectfully submits that the Examiner's rejections of the claims are unsupported by the facts in the record. Accordingly, Appellant requests that the Board reverse the Examiner's rejections of Claims 41, 42, 44-48, 50-54, 56-63, 65-68, 70-87, and 91-94 and issue a Notice of Allowance.

The Commissioner is hereby authorized to charge payment of any of the following fees that may be applicable to this communication, or credit any overpayment, to **Deposit Account No. 23-3178**: (1) any filing fees required under 37 CFR § 1.16; (2) any patent application and reexamination processing fees under 37 CFR § 1.17; and/or (3) any post issuance fees under 37 CFR § 1.20. In addition, if any additional extension of time is required, which has not otherwise been requested, please consider this a petition therefore and charge any additional fees that may be required to **Deposit Account No. 23-3178**.

Respectfully submitted,

Dated: October 14, 2011

By: /John M. Guynn/
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VIII. CLAIMS APPENDIX

Claims 1-40 (Cancelled).

41. A dental bleaching composition that is substantially free of abrasives for non-abrasively bleaching and desensitizing a person's teeth, comprising:

a dental bleaching agent in an amount in a range of 10% to about 30% by weight of the dental bleaching composition so as to have a tooth bleaching effect when contacted with a person's teeth, said dental bleaching agent comprising at least one peroxide;

potassium nitrate in a range of about 0.01% to less than 2% by weight of the dental bleaching composition so as to result in reduced tooth sensitivity that may be caused by said dental bleaching agent in the absence of said potassium nitrate when the dental bleaching composition is contacted with a person's teeth for a time sufficient to bleach teeth; and

a carrier into which said dental bleaching agent and potassium nitrate are dispersed, the carrier being free of an amount of an abrasive that would externally abrade a tooth surface such that the dental bleaching composition does not externally abrade a tooth surface when applied thereto, the carrier comprising a solvent and a tackifying agent.

42. A dental bleaching composition as defined in claim 41, said dental bleaching agent comprising at least one of hydrogen peroxide, carbamide peroxide, sodium perborate, benzoyl peroxide, or glycerol peroxide.

43. (Cancelled)

44. A dental bleaching composition as defined in claim 41, wherein said dental bleaching agent is included in a range of 10% to about 20% by weight of the dental bleaching composition.

45. A dental bleaching composition as defined in claim 41, wherein said dental bleaching agent is included in a range of 10% to 15% by weight of the dental bleaching composition.

46. A dental bleaching composition as defined in claim 41, wherein said potassium nitrate has a concentration of about 0.5% by weight of the dental bleaching composition.

47. A dental bleaching composition as defined in claim 41, said carrier comprising a polyol.

48. A dental bleaching composition as defined in claim 47, said polyol comprising at least one of glycerin, propylene glycol, polypropylene glycol, polyethylene glycol, erythritol, sorbitol, or mannitol.

49. (Cancelled)

50. A dental bleaching composition as defined in claim 41, said tackifying agent comprising at least one of carboxypolymethylene, a gum, or a protein.

51. A dental bleaching composition as defined in claim 41, said carrier comprising water.

52. A dental bleaching composition as defined in claim 41, further comprising an antimicrobial agent that is at least one of chlorhexidine, tetracycline, cetyl pyridinium chloride, benzalkonium chloride, cetyl pyridinium bromide, methyl benzoate, or propyl benzoate.

53. A dental bleaching composition as defined in claim 41, further comprising an anticariogenic agent that is at least one of sodium monofluorophosphate, sodium fluoride, or stannous fluoride.

54. A dental bleaching composition as defined in claim 41, further comprising at least one bleaching agent stabilizer that is at least one of EDTA, a salt of EDTA, adipic acid, succinic acid, citric acid, a nitrate of tin, or a phosphate of tin.

55. (Cancelled)

56. A dental bleaching composition as defined in claim 41, wherein said potassium nitrate reduces sensitivity to at least one of hot or cold.

57. A dental bleaching composition as defined in claim 41, wherein said potassium nitrate reduces at least one of gum, tongue, or throat sensitivity.

58. A dental bleaching composition as defined in claim 41, wherein said potassium nitrate further enhances whitening of teeth by said dental bleaching agent.

59. A dental bleaching composition that is substantially free of abrasives for non-abrasively bleaching and desensitizing a person's teeth, comprising:

a dental bleaching agent in an amount in a range of 10% to about 20% by weight of the dental bleaching composition so as to have a tooth bleaching effect when contacted with a person's teeth, said dental bleaching agent comprising at least one peroxide;

potassium nitrate in a range of about 0.05% to about 1% by weight of the dental bleaching composition so as to result in reduced sensitivity that may be caused by said dental bleaching agent in the absence of said potassium nitrate when the dental bleaching composition is passively maintained in contact with a person's teeth for at least about 15 minutes without brushing or scrubbing; and

a carrier into which said dental bleaching agent and potassium nitrate are dispersed, the carrier being free of an amount of an abrasive that would externally abrade a tooth surface such that the dental bleaching composition does not externally abrade a tooth surface when applied thereto, the carrier comprising a solvent and a tackifying agent.

60. A dental bleaching composition as defined in claim 59, said dental bleaching agent comprising at least one of hydrogen peroxide or carbamide peroxide.

61. A dental bleaching composition as defined in claim 59, wherein said potassium nitrate has a concentration of about 0.5% by weight of the dental bleaching composition.

62. A dental bleaching composition as defined in claim 59, said carrier comprising a polyol and a tackifying agent.

63. A dental bleaching composition as defined in claim 59, further comprising at least one of an antimicrobial agent, an anticariogenic agent, or a bleaching agent stabilizer.

64. (Cancelled)

65. A dental bleaching composition that is substantially free of abrasives for non-abrasively bleaching and desensitizing a person's teeth, comprising:

a dental bleaching agent in an amount in a range of 10% to about 30% by weight of the dental bleaching composition so as to have a tooth bleaching effect when contacted with a person's teeth, said dental bleaching agent comprising at least one peroxide;

potassium nitrate in an amount of about 0.5% by weight of the dental bleaching composition so as to result in reduced tooth sensitivity that may be caused by said dental bleaching agent in the absence of said potassium nitrate when the dental bleaching composition is contacted with a person's teeth for a time sufficient to bleach teeth; and

a carrier into which said dental bleaching agent and potassium nitrate are dispersed, the carrier being free of an amount of an abrasive that would externally abrade a tooth surface such that the dental bleaching composition does not externally abrade a tooth surface when applied thereto, the carrier comprising a solvent and a tackifying agent.

66. A dental bleaching composition as defined in claim 65, said dental bleaching agent comprising at least one of hydrogen peroxide or carbamide peroxide.

67. A dental bleaching composition as defined in claim 65, said carrier comprising a polyol and a tackifying agent.

68. A dental bleaching composition as defined in claim 65, said carrier comprising water.

69. (Cancelled)

70. A dental bleaching composition as defined in claim 65, wherein said potassium nitrate reduces sensitivity to at least one of hot or cold.

71. A dental bleaching composition as defined in claim 65, wherein said potassium nitrate reduces at least one of gum, tongue, or throat sensitivity.

72. A method for non-abrasively bleaching and desensitizing a person's teeth, comprising:

providing a non-abrasive dental bleaching composition comprising:

a dental bleaching agent in an amount in a range of 10% to about 30% by weight of the dental bleaching composition so as to have a tooth bleaching effect when contacted with a person's teeth, said dental bleaching agent comprising at least one peroxide;

potassium nitrate in a range of about 0.01 to less than 2% by weight of the dental bleaching composition so as to result in reduced tooth sensitivity that may be caused by said dental bleaching agent in the absence of said potassium nitrate when the dental bleaching composition is contacted with a person's teeth for a time sufficient to bleach teeth; and

a carrier into which said dental bleaching agent and potassium nitrate are dispersed, the carrier being free of an amount of an abrasive that would externally abrade a tooth surface such that the dental bleaching composition does not externally abrade a tooth surface when applied thereto, the carrier comprising a solvent and a tackifying agent; and

contacting the person's teeth with said non-abrasive dental bleaching composition without scrubbing or brushing for a time sufficient to bleach teeth and in a manner so as to not abrade the person's teeth,

said potassium nitrate reducing tooth sensitivity that may be caused by said dental bleaching agent in the absence of said potassium nitrate.

73. A method as defined in claim 72, wherein contacting the person's teeth with said dental bleaching composition without scrubbing or brushing further comprises:

introducing a quantity of said dental bleaching composition into a dental tray; and

placing the dental tray over the person's teeth in order for the dental bleaching composition to contact the person's teeth for the time sufficient to bleach teeth, the dental bleaching composition helping to adhere the dental tray to the person's teeth.

74. A method as defined in claim 73, wherein the dental tray remains in place over the person's teeth for at least about 15 minutes.

75. A method as defined in claim 73, wherein the dental tray remains in place over the person's teeth for at least about 1 hour.

76. A method as defined in claim 73, wherein the dental tray remains in place over the person's teeth for at least about 2 hours.

77. A method for non-abrasively bleaching and desensitizing a person's teeth, comprising:

providing a non-abrasive dental bleaching composition comprising:

a dental bleaching agent in an amount in a range of 10% to about 20% by weight of the dental bleaching composition so as to have a tooth bleaching effect when contacted with a person's teeth, said dental bleaching agent comprising at least one peroxide;

potassium nitrate in a range of about 0.05% to about 1% by weight of the dental bleaching composition so as to result in reduced tooth sensitivity that may be caused by said dental bleaching agent in the absence of said potassium nitrate when the dental bleaching composition is contacted with a person's teeth for a time sufficient to bleach teeth; and

a carrier into which said dental bleaching agent and potassium nitrate are dispersed, the carrier being free of an amount of an abrasive that would externally

abrade a tooth surface such that the dental bleaching composition does not externally abrade a tooth surface when applied thereto, the carrier comprising a solvent and a tackifying agent; and

contacting the person's teeth with said dental bleaching composition for at least about 15 minutes without scrubbing or brushing and in a manner so as to not abrade the person's teeth,

said potassium nitrate reducing tooth sensitivity that may be caused by said dental bleaching agent in the absence of said potassium nitrate.

78. A method as defined in claim 77, wherein contacting the person's teeth with said dental bleaching composition without scrubbing or brushing further comprises:

introducing a quantity of said dental bleaching composition into a dental tray; and

placing the dental tray over the person's teeth for at least about 15 minutes in order for the dental bleaching composition to contact the person's teeth, the dental bleaching composition helping to adhere the dental tray to the person's teeth.

79. A method as defined in claim 78, wherein the dental tray remains in place over the person's teeth for at least about 1 hour.

80. A method as defined in claim 78, wherein the dental tray remains in place over the person's teeth for at least about 2 hours.

81. A method for non-abrasively bleaching and desensitizing a person's teeth, comprising:

providing a non-abrasive dental bleaching composition comprising:

a dental bleaching agent in an amount in a range of 10% to about 30% by weight of the dental bleaching composition so as to have a tooth bleaching effect when contacted with a person's teeth, said dental bleaching agent comprising at least one peroxide;

potassium nitrate in an amount of about 0.5% by weight of the dental bleaching composition so as to result in reduced tooth sensitivity that may be caused

by said dental bleaching agent in the absence of said potassium nitrate when the dental bleaching composition is contacted with a person's teeth for a time sufficient to bleach teeth; and

a carrier into which said dental bleaching agent and potassium nitrate are dispersed, the carrier being free of an amount of an abrasive that would externally abrade a tooth surface such that the dental bleaching composition does not externally abrade a tooth surface when applied thereto, the carrier comprising a solvent and a tackifying agent; and

contacting the person's teeth with said dental bleaching composition without scrubbing or brushing for a desired time period and in a manner so as to not abrade the person's teeth,

said potassium nitrate reducing tooth sensitivity that may be caused by said dental bleaching agent in the absence of said potassium nitrate.

82. A method as defined in claim 81, wherein contacting the person's teeth with said dental bleaching composition without scrubbing or brushing further comprises:

introducing a quantity of said dental bleaching composition into a dental tray; and

placing the dental tray over the person's teeth in order for the dental bleaching composition to contact the person's teeth for the time sufficient to bleach teeth, the dental bleaching composition helping to adhere the dental tray to the person's teeth.

83. A method as defined in claim 82, wherein the dental tray remains in place over the person's teeth for at least about 15 minutes.

84. A method as defined in claim 82, wherein the dental tray remains in place over the person's teeth for at least about 1 hour.

85. A method as defined in claim 82, wherein the dental tray remains in place over the person's teeth for at least about 2 hours.

86. A sticky and viscous, dental bleaching composition that is substantially free of abrasives for non-abrasively bleaching and desensitizing a person's teeth, comprising:

a dental bleaching agent in an amount in a range of 10% to about 20% by weight of the dental bleaching composition so as to have a tooth bleaching effect when contacted with a person's teeth, said dental bleaching agent comprising at least one peroxide;

potassium nitrate in a range of about 0.01% to less than 2% by weight of the dental bleaching composition so as to result in reduced tooth sensitivity that may be caused by said dental bleaching agent in the absence of said potassium nitrate when the dental bleaching composition is contacted with a person's teeth for a time sufficient to bleach teeth; and

a carrier into which said dental bleaching agent and potassium nitrate are dispersed, the carrier being free of an amount of an abrasive that would externally abrade a tooth surface such that the dental bleaching composition does not externally abrade a tooth surface when applied thereto, the carrier comprising a solvent and a tackifying agent.

87. A dental bleaching composition as defined in claim 86, wherein said tackifying agent is selected from the group comprising carboxypolymethylene, polyacrylic acid copolymers, gums, polyethylene oxides, proteins, and mixtures thereof.

Claims 88-90 (Cancelled).

91. A dental bleaching composition as defined in claim 59, wherein said dental bleaching agent is included in a range of 10% to 15% by weight of the dental bleaching composition.

92. A dental bleaching composition as defined in claim 65, wherein said dental bleaching agent is included in a range of 10% to about 20% by weight of the dental bleaching composition.

93. A dental bleaching composition as defined in claim 86, wherein the bleaching agent in a range of 10% to 15% by weight of the dental bleaching composition.

94. A dental bleaching composition as defined in claim 46, wherein said dental bleaching agent is included in a range of 10% to 15% by weight of the dental bleaching composition.

IX. EVIDENCE APPENDIX

The Declaration of Dan E. Fischer, DDS under 37 C.F.R. §§ 1.131, previously filed and made of record together with Preliminary Amendment "A" on June 25, 2001, is attached hereto.

EXPRESS MAIL LABEL NO. EL813291105US

PATENT APPLICATION
Docket No: 7678.350.2

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of	Steven D. Jensen and Dan E. Fischer, DDS	
Serial No.	09/710,181	Art Unit 1619
Conf. No.	4245	
Filed:	November 10, 2000	
For:	COMPOSITIONS AND METHODS FOR WHITENING AND DESENSITIZING TEETH	
Examiner:	Raj Bawa, Ph.D.	

DECLARATION UNDER 37 C.F.R. § 1.131
OF DAN E. FISCHER, DDS

The Assistant Commissioner of Patents
and Trademarks
Washington, D. C. 20231

Sir:

I, Dan E. Fischer, DDS, declare as follows:

1. I am one of the named co-inventors of the subject matter disclosed and claimed in the above-identified application, and I am personally knowledgeable of the facts stated herein.

2. Steven D. Jensen is the other named co-inventor of the subject matter disclosed and claimed in the above-identified application.

3. The above-identified application has been assigned to Ultradent Products, Inc. ("Ultradent"), located at 505 West, 10200 South in South Jordan, Utah.

4. The subject matter claimed in the above-identified application is the result of a joint effort between me and Steven D. Jensen.

5. I obtained a doctorate of dental surgery from Loma Linda University, located in Loma Linda, California, in 1974, am currently the president of Ultradent, and continue to practice dentistry in addition to my duties as President of Ultradent, therefore making me knowledgeable in the field of dentistry.

6. The above-identified application discloses and claims desensitizing dental bleaching compositions that comprise a dental bleaching agent, such as carbamide peroxide, and potassium nitrate as a desensitizing agent, both of which are dispersed in an appropriate carrier.

7. Potassium nitrate is known to be an effective desensitizing agent for teeth, as described and claimed in U.S. Patent Nos. 5,851,512 and 5,855,870, both of which are assigned to Ultradent Products, Inc. and which name Steven D. Jensen and myself as co-inventors (Mr. Jensen having been added as a co-inventor after issuance).

8. A desensitizing dental composition containing 3% by weight potassium nitrate, used to alleviate sensitivity associated with home-use dental bleaching compositions, and covered by U.S. Patent Nos. 5,851,512 and 5,855,870, is available from Ultradent Products, Inc. under the trade name ULTRA EZ.

9. It is my understanding, as one knowledgeable in the field of dentistry, that the standard concentration of potassium nitrate within desensitizing dental compositions is about 3-5% by weight.

10. Subsequent to the filing of U.S. Patent Nos. 5,851,512 and 5,855,870, it was discovered that potassium nitrate can, in some cases, when included within a dental bleaching composition in certain concentrations, also enhance the whitening ability of a dental bleaching composition compared to bleaching compositions that do not include potassium nitrate, as described

in U.S. application Serial No. 09/494,113, filed January 31, 2000, now abandoned, in addition to providing a desensitizing effect.

11. Although it is and has been customary to include at least 3% potassium nitrate within desensitizing dental compositions, we discovered, by means of an extensive comparative study summarized in the above-identified application, that potassium nitrate, when included within a dental bleaching composition at concentration of only 0.5% by weight, unexpectedly and surprisingly provides significantly higher degrees of both desensitization and whitening compared to compositions that include either 3% potassium nitrate or no potassium nitrate.

12. As set forth at page 26, line 1, through page 29, line 4, of the above-identified application, five (5) dental bleaching compositions (identified as compositions A-E, respectively) having the following amounts of carbamide peroxide and potassium nitrate were prepared and comparatively tested:

Composition	Carbamide Peroxide	KNO_3
A	10%	0%
B	10%	3%
C	10%	3%
D	15%	3%
E	10.5%	0.5%

13. The results of the comparative study were summarized in the following table found at page 28, lines 1-17, of the above-identified application, with a description of what is meant by each column of data provided beneath the table:

1	2	3	4	5	6	7	8	9
A	266	37 (13.9)	40 (15)	2 (0.8)	3 (1.1)	14	7	5.4
B	294	51 (17.3)	50 (17)	14 (4.8)	3 (1)	17	6	4.6
C	279	65 (23.3)	45 (16.1)	4 (1.4)	3 (1.1)	17	6	6.7
D	256	61 (23.9)	70 (27.6)	13 (5.1)	2 (0.8)	18	2	7.5
E	216	14 (5.3)	4 (2.1)	0 (0)	0 (0)	7	11	8.6

Column 1 = Composition Tested
Column 2 = Total number of days used by all patients in group
Column 3 = Number of days sensitive to hot or cold (% of total days)
Column 4 = Number of days gums sensitive (% of total days)
Column 5 = Number of days tongue sensitive (% of total days)
Column 6 = Number of days throat sensitive (% of total days)
Column 7 = Number of patients reporting sensitivity to anything
Column 8 = Number of patients reporting no sensitivity to anything
Column 9 = Average number of shade tab changes

14. As indicated by the data set forth in ¶13 above, the comparative study also surprisingly and unexpectedly indicated that potassium nitrate, when included in a concentration of 3% by weight within dental bleaching compositions having 10% or 15% by weight carbamide peroxide (compositions B-D), actually caused *increased sensitivity*, on average, to hot or cold, as well as greater tongue sensitivity, compared to composition A, which included 10% carbamide peroxide and *no* potassium nitrate.

15. The comparative study thus demonstrated the surprising and unexpected result that potassium nitrate, when blended with a dental bleaching agent in a dental bleaching composition used to bleach teeth, does not behave as a desensitizing agent at all concentrations, particularly at higher concentrations such as 3%.

16. Because potassium nitrate was known to be a desensitizing agent, and is customarily included in amounts of about 3-5% within desensitizing dental compositions, one of ordinary skill in the art, when reading U.S. Patent Nos. 5,851,512 and 5,855,870, which teach the inclusion of a

dental bleaching agent together with potassium nitrate in a single composition to both bleach and desensitize teeth in a single step, would have expected potassium nitrate to provide desensitizing properties within the standard concentration range of about 3-5%.

17. However, the comparative study, as summarized in the above-identified application, demonstrated the entirely counterintuitive and surprising result of potassium nitrate providing much greater desensitization when used within a dental bleaching composition at a concentration of only 0.5% compared to when it was included in a concentration of 3%.

18. Even more surprisingly and unexpectedly, the dental bleaching composition that included 0.5% potassium nitrate and 10.5% carbamide peroxide (composition E) also provided significantly better whitening of teeth compared to compositions that included either no potassium nitrate (composition A) or 3% potassium nitrate (compositions B-D), even better than composition B, which included 3% potassium nitrate and a higher concentration of carbamide peroxide (15%).

19. In particular, the composition that included 0.5% potassium nitrate (composition E) resulted, on average, in a total of 8.9 shade tab changes during the duration of the study, whereas the composition that included no potassium nitrate (composition A) resulted, on average, in a total of 5.4 shade tab changes, while the compositions that include 3% potassium nitrate (compositions B-D) resulted, on average, in a total of 4.6, 6.7 and 7.5 shade tab changes, respectively.

20. In summary, the comparative study demonstrated the superiority of including 0.5% potassium nitrate within a desensitizing dental bleaching composition compared to either including no potassium nitrate or 3% potassium nitrate, in terms of significantly decreased tooth sensitivity and significantly increased tooth whitening, both of which were surprising and unexpected based upon conventional knowledge at the time of the invention.

21. For example, Den-Mat, Inc. currently sells, and, on information and belief, has sold since before the filing date of the above-identified application, a dental bleaching gel that includes

a dental bleaching agent and potassium nitrate in an amount of about 5% by weight under the trade name REMBRANDT XTRA COMFORT, as indicted by an advertisement in the Dental Products Report published in November 1998.

22. In order to determine the actual concentration of potassium nitrate, a commercially available sample of REMBRANDT XTRA COMFORT was obtained and analyzed, as was a sample of Ultradent's own 0.5% potassium nitrate dental bleaching composition currently sold under the name of OPALESCENCE PF in order to confirm the accuracy of the testing method.

23. As evidenced by the analysis summarized in Exhibit A attached hereto, it was determined that REMBRANDT XTRA COMFORT includes 17% by weight carbamide peroxide and 5.17% by weight potassium nitrate, which is about 2-1/2 times greater than the upper range limit of "about 2% by weight" potassium nitrate recited in the broadest claim of the above-identified application, about 5 times greater than the upper limit of the more preferred range ("about 1% by weight"), and about 10 times greater than the most preferred amount of "about 0.5% by weight" potassium nitrate.

24. I declare further that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful, false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful, false statements may jeopardize the validity of the application or any patent issuing thereon.

Signed at Salt Lake City, Utah, this 15 day of June 2001.

Dan E. Fischer, D.D.S.

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Exhibit A

ULTRADENT PRODUCTS, INC.
The Syringe People™

II. Analyses Performed:

Samples AD 2869 were analyzed for % carbamide peroxide (CPO) using procedure TST 21.4. Samples AD 2869 were analyzed for % sodium fluoride using TST 52.4. Fluoride (F^-) content was recorded as sodium fluoride (NaF). Nitrate (NO_3) determination was done on all samples by IC using the Shimadzu system. The nitrate concentration was recorded as potassium nitrate (KNO_3). Opalescence PF 20% Melon was analyzed as a control sample. Each product was analyzed at least twice for tests performed and tests were analyzed from different syringes.

III. Results:

Product	Peroxide Results	Label Claim	Fluoride Results	Label Claim	Nitrate Results
Rembrandt (AD 2869)	17.0% (m/m) CPO	16% CPO	N/A	N/A	5.17% (m/m) KNO_3
Opalescence PF 20% Melon Batch: FKABF W/O#: W43QH	19.9% (m/m) CPO	20% CPO	0.2562% (m/m) NaF	0.11% F^- 0.25% NaF	0.48% (m/m) KNO_3 0.50% (m/m) Claim

Reviewed by: Fareed Ansari

Signature: Fareed Ansari

Date: 5/25/01

Analyst: Anna Lee Wilson/ Fred Williams

Signature: Anna Lee Wilson

Signature: Fred Williams

Book #: 1239 Page #: 24, 27, 28, 29

Book#: 1281 Page #: 2, 8, 15

Date: 5/25/01

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X. RELATED PROCEEDINGS APPENDIX

None